INTERNATIONAL STANDARD

ISO 10651-5

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Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 5: Gas-powered emergency resuscitators

Ventilateurs pulmonaires à usage médical — Exigences particulières pour la sécurité de base et les performances essentielles —

Partie 5: Appareils de réanimation d'urgence alimentés par gaz

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10651-5 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 10651-5, together with ISO 10651-4:2002, cancels and replaces ISO 8382:1988, which has been technically revised.

ISO 10651 consists of the following parts, under the general title *Lung ventilators for medical use — Particular requirements for basic safety and essential performance*:

— *Part 2: Home care ventilators for ventilator-dependent patients*

— *Part 3: Particular requirements for emergency and transport ventilators*

— *Part 4: Particular requirements for operator-powered resuscitators*

— *Part 5: Gas-powered emergency resuscitators*

— *Part 6: Home-care ventilatory support devices*

NOTE ISO 10651-1:1993, *Lung ventilators for medical use — Part 1: Requirements*, was withdrawn in 2001 and has been revised as IEC 60601-2-12:2001, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators*.

Introduction

For victims whose lives are at risk from respiratory failure, in particular during cardiac arrest, resuscitation councils and associations teach that the best ultimate outcome will be achieved if there is a continuous chain of care starting with earliest possible bystander **cardiopulmonary resuscitation** and continuing until the victim can be put under professional medical care. In order to improve the care possible at the early stages of this chain, authorities and organizations are training non-specialized personnel in key situations, such as where people congregate or where there are increased risks, so that they can be available to provide a higher level of care with a minimum of delay.

There is a growing realization that the effectiveness of such intervention can be greatly enhanced by the use of certain basic **equipment**, such as that which provides ventilation whilst avoiding mouth-to-mouth contact. Simple, **gas-powered emergency resuscitators** can deliver controlled ventilation for this purpose and this document specifies the criteria they are required to satisfy.

In this part of ISO 10651, the following symbols and notations are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes, explanations, advice, introductions, general statements and references: smaller roman type;

— test specifications: *italic type*;

— terms defined in ISO 4135:2001, IEC 60601-1:1988 or in this part of ISO 10651: **bold type**.

Throughout this part of ISO 10651, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 5: Gas-powered emergency resuscitators

1 * Scope

This part of ISO 10651 specifies the basic safety and essential performance requirements for **gas-powered emergency resuscitators** (3.10) intended for use with humans by **first responders**. This **equipment** is intended for emergency field use and is intended to be continuously **operator** attended in **normal use**.

This part of ISO 10651 also specifies the requirements for **resuscitator sets** (3.22).

This part of ISO 10651 is not applicable to electrically-powered **resuscitators**.

NOTE ISO 10651-3 covers emergency and transport ventilators.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31 (all parts), *Quantities and units*

ISO 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10297, *Gas cylinders — Refillable gas cylinder valves — Specification and type testing*

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices* and Amendment 1:2003

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied* and Amendment 1:2002 and Amendment 2:2004

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* and Amendment 1:1991 and Amendment 2:1995

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:1988 and the following apply. For convenience, the sources of all defined terms used in this document are given in Annex E.

3.1
accompanying documents
documents accompanying **resuscitator** or **resuscitator sets** and containing all important information for the **user**, **operator**, installer or assembler of the **resuscitator**, particularly regarding safety

NOTE Adapted from IEC 60601-1:1988, definition 2.1.4.

3.2
automatic pressure-cycled resuscitator
resuscitator in which the cycling from the **inspiratory phase** to the **expiratory phase** occurs after attaining a pressure determined by the control setting

3.3
automatic time-cycled resuscitator
resuscitator in which the cycling between the **inspiratory phase** and **expiratory phase** is controlled automatically at time intervals determined by the control setting

3.4
automatic volume-cycled resuscitator
resuscitator in which the cycling from the **inspiratory phase** to the **expiratory phase** occurs after the delivery of a **delivered volume** determined by the control setting

3.5
cardiopulmonary resuscitation
combination of rescue breathing and chest compressions delivered to victims thought to be in cardiac arrest

[*AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Care*]

3.6
clearly legible
capable of being read by the **operator** or other relevant person with normal vision

NOTE See also 8.2.1.

3.7
*** delivered volume**
V_{del}
volume of gas delivered through the **patient connection port** during an **inspiratory phase**

3.8
demand valve
part of the **resuscitator** that delivers a flow of gas related to a reduction of pressure generated by the **patient** at the **patient connection port**

3.9
first responder
individual who has been trained to provide primary response to a respiratory emergency

EXAMPLE 1 Fire fighter.

EXAMPLE 2 Emergency medical technician.

3.10
gas-powered emergency resuscitator
resuscitator
portable **equipment**, powered by compressed gas, intended for immediate use to provide lung ventilation in the resuscitation of individuals who have sudden breathing difficulties

3.11
inadvertent positive end-expiratory pressure
inadvertent PEEP
unintended positive pressure at the **patient connection port** at the end of the **expiratory phase**

3.12
intermediate hose
hose that conducts gas between parts of the **resuscitator**

3.13
manually-cycled resuscitator
resuscitator in which the **inspiratory phase** and **expiratory phase** are controlled by a repeated manual action of the **operator**

NOTE A **demand valve** that can be overridden with a manual trigger is, for the purposes of this document, classified as a 'manually-cycled resuscitator incorporating a demand valve' and not as a 'demand valve' as they are commonly termed in some countries.

3.14
minute volume
$\dot{V}$
volume of gas per minute entering or leaving the **patient's** lungs

3.15
operator
person handling the **resuscitator**

NOTE Adapted from IEC 60601-1:1988, definition 2.12.17.

3.16
patient-triggered resuscitator
resuscitator in which the cycling from the **expiratory phase** to the **inspiratory phase** is triggered by an inspiratory effort of the **patient**

3.17
patient-triggering
mode of operation in which a reduction of pressure generated by the **patient** at the **patient connection port** initiates the set **inspiratory phase**

3.18
patient valve
valve in the **resuscitator breathing system** that directs gas into the lungs during the **inspiratory phase** and from the lungs into the atmosphere during the **expiratory phase**

3.19
pressure-limiting device
means for limiting the maximum pressure within the **resuscitator breathing system**

3.20
resuscitator breathing system
breathing system bounded by the **low-pressure gas input port(s)**, the gas intake port(s) and the **patient connection port**, together with the **fresh gas intake port** and **exhaust port(s)**, if these are provided

3.21
resuscitator dead space
volume of previously exhaled gas within the **resuscitator breathing system** that is delivered to the **patient** in the succeeding **inspiratory phase**

3.22
resuscitator set
pack of all the necessary components that enable the **resuscitator** to be carried to the site of a resuscitation emergency and that enable the **resuscitator** to be made ready for immediate use

3.23
safety hazard
potentially detrimental effect on the **patient**, other persons, animals, or the surroundings, arising directly from the **resuscitator**

NOTE Adapted from IEC 60601-1:1988, definition 2.12.18.

3.24
single fault condition
condition in which a single means for protection against a **safety hazard** in the **resuscitator** is defective or a single external abnormal condition is present

NOTE Adapted from IEC 60601-1:1988, definition 2.10.11.

4 General requirements

4.1 General

The **resuscitator** shall, when transported, stored, installed, operated in **normal use**, and maintained according to the **accompanying documents**, cause no **safety hazard** that could reasonably be foreseen and that is not connected with its intended application, in **normal condition** and in **single fault condition**.

A **risk management process** complying with ISO 14971 shall be performed.

In applying ISO 14971:

a) the term “medical device” shall assume the same meaning as **resuscitator**;

b) the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, **single fault conditions** identified in this part of ISO 10651;

c) where this part of ISO 10651 specifies measurable requirements addressing particular **risks**, and these requirements are complied with, the **residual risks** of these requirements shall be presumed to be acceptable unless there is **objective evidence** to the contrary.

This part of ISO 10651 specifies requirements that are generally applicable to **risks** associated with **resuscitators**, and is intended to serve as a tool during the **risk management process**. The **risk management process** identifies not only those **safety hazards** addressed by this part of ISO 10651, but also all **safety hazards**, their associated **risks** and **risk control** measures.

Conditions or faults that can give rise to **safety hazards** are identified in the clauses of this part of ISO 10651. In these cases, it will often be necessary to carry out a **risk management process** to determine what the actual **safety hazards** are and the tests that need to be done to show that the identified **safety hazards** do not arise in the specified circumstance.

It is recognized that the manufacturer might not be able to follow all the processes identified in this part of ISO 10651 for each constituent component of the **resuscitator**, such as proprietary components, subsystems of non-medical origin, and legacy parts. In this case, the manufacturer should take special account of the need for additional **risk control** measures.

Where requirements of this part of ISO 10651 refer to freedom from unacceptable **risk**, the manufacturer, in accordance with the manufacturer’s policy for determining acceptable **risk,** determines the acceptability or unacceptability of this **risk**.

*Check compliance by inspection of the **risk management file**. The requirements of this clause and all requirements of this part of ISO 10651 referring to inspection of the **risk management file** are considered to be satisfied if the manufacturer has*

— established a risk management process,

— established acceptable levels of risk, and

— demonstrated that the residual risk is acceptable (in accordance with the policy for determining acceptable risk).

4.2 Other test methods

The manufacturer may use type tests different from those detailed within this part of ISO 10651 if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.3 Acceptance criteria

Many of the test clauses within this part of ISO 10651 establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the manufacturer chooses to specify in the **accompanying documents** higher performance levels than those specified within this part of ISO 10651, these manufacturer-specified levels become the acceptance levels and shall also be met.

5 Constructional requirements

5.1 General

5.1.1 Materials of construction

All gas conducting parts shall be constructed from materials selected to take into account the chemical and physical properties of any substances that the **accompanying documents** indicate:

— can be administered through the **resuscitator**, and

— can be used to clean and disinfect or sterilize the **resuscitator**.

*Check compliance by inspection of the **risk management file**.*

5.1.2 Surfaces, corners and edges

Rough surfaces, sharp corners, open ends of tubular components and edges that can cause injury or damage shall be avoided or covered. Particular attention shall be paid to the removal of burrs.

Check compliance by inspection.

5.1.3 Leaching of substances

The **resuscitator** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the **resuscitator** or its components during use. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during **normal use**.

*Check compliance by inspection of the **risk management file**.*

5.1.4 Breathing tubes

Breathing tubes with an internal diameter of more than 18 mm, intended for use in the **resuscitator breathing system**, shall comply with ISO 5367.

Check compliance by application of the requirements of ISO 5367.

5.1.5 Supply of sterile components

If a claim is made in the labelling that a product is sterile, it shall have been sterilized using an appropriate, validated method, as described in ISO 11134, ISO 11135, ISO 11137, ISO 11138, or ISO 14937.

The packaging for **resuscitators** or parts supplied sterile shall meet the requirements of ISO 11607. Such packaging shall not be capable of re-closure without clearly revealing that it has been opened.

Non-sterile packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

*Check compliance by a review of the **accompanying documents** for methods of sterilization and disinfection and by inspection of the relevant validation reports.*

5.1.6 * Breathing system filter

Any **breathing system filter**, either incorporated into the **resuscitator** or indicated in the **accompanying documents** for use with the **resuscitator**, shall comply with the applicable parts of ISO 23328-1 and ISO 23328-2.

Check compliance by application of the requirements of ISO 23328-1 and ISO 23328-2.

5.1.7 Arrangement of functions

Any **single fault condition** shall not cause any monitoring or alarm system function, as specified in this part of ISO 10651, and the corresponding ventilation control function to fail in such a way that the monitoring or alarm system function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored **resuscitator** function.

Check compliance by simulation of a ***single fault condition*** *and visual inspection.*

5.1.8 Protection against accidental adjustments

Means of protection against accidental alteration of control settings, including the “on-off” switch, shall be provided. Mechanical techniques such as locks, shielding, friction-loading and detents may be used.

Check compliance by visual inspection following the instructions for use.

5.1.9 Selector switches/controls

For controls that are not continuously variable, means shall be provided that prevent the selector from remaining in an intermediate position.

EXAMPLE 1 An “on-off” switch.

EXAMPLE 2 An oxygen concentration selector.

EXAMPLE 3 A selector for preset, discrete values of **delivered volume** or frequency.

Check compliance by inspection.

5.1.10 Accuracy of operating data

While the **resuscitator** is in **normal use**, it shall deliver ventilation accuracy as indicated in the instructions for use. See also 8.3.2.2.

Verify compliance, by means of the appropriate test methods described in this part of ISO 10651.

5.1.11 * Resuscitator set

The **resuscitator** shall be supplied with or the **accompanying documents** shall recommend a **resuscitator set,** including a medical gas supply system that complies with the relevant requirements of this part of ISO 10651.

Check compliance by inspection.

5.2 Connectors

5.2.1 Connection to the medical gas supply system

If a detachable hose assembly is provided for connection between the **resuscitator** and the medical gas supply system, it shall comply with ISO 5359. If a hose assembly is permanently connected to the **resuscitator**, the connection to the medical gas supply system shall be by means of:

— either a probe complying with ISO 9170-1, or

— a permanent connector.

NOTE A permanent connector is one that can be separated only by use of a tool.

Check compliance by inspection.

5.2.2 Connection to the high-pressure gas input port

The connection of the hose to the **high-pressure gas input port** of the **resuscitator** shall be by means of:

- a non-interchangeable, screw-threaded connector complying with ISO 5359,
- a probe complying with ISO 9170-1, or
- a permanent connector.

Check compliance by inspection.

5.2.3 Patient connection port connector

The **patient connection port** connector of the **resuscitator** shall be a coaxial 15 mm / 22 mm connector complying with ISO 5356-1.

Check compliance by application of the requirements of ISO 5356-1.

5.2.4 Facemask connector

Facemasks shall have either a 22 mm female connector or a 15 mm male connector that shall mate with the corresponding connectors specified in ISO 5356-1.

Check compliance by application of the requirements of ISO 5356-1.

5.2.5 * Gas exhaust port connector

If a gas **exhaust port** connector is provided, it shall be:

- a 30 mm male conical connector complying with ISO 5356-1; or
- a proprietary connector incompatible with ISO 5356-1 and ISO 9170-1 having a means to prevent the connection of any breathing attachment conforming to ISO 5356-1 or ISO 5356-2 to the internal lumen.

Check compliance by inspection and by application of the requirements of ISO 5356-1 or ISO 5356-2 and ISO 9170-1.

5.2.6 Resuscitator inspiratory limb connectors

Connectors in the inspiratory limb of the **resuscitator**, if conical, shall comply with ISO 5356-1 and ISO 5356-2.

Non-conical connectors shall not engage with conical connectors complying with ISO 5356-1 or ISO 5356-2 unless they comply with the engagement, disengagement and leakage requirements of ISO 5356-1 or ISO 5356-2.

Check compliance by inspection.

5.2.7 Emergency air intake port

An emergency air intake port shall:

- be provided,
- comply with the requirements of 7.1.2.2 and 7.1.2.3, and

— not accept any connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by inspection.

6 Operational requirements

6.1 General

6.1.1 * Patient valve function after contamination with vomitus

When the **resuscitator** is tested in accordance with the test described in B.3.1, the time for cleaning and restoration to normal function shall not exceed 20 s. It shall then meet the requirements specified in Clause 7. The valve housing should be constructed so that operation of the mechanism can be observed by the **operator**, e.g. through a transparent housing.

NOTE Observation of the functioning mechanism of the **patient valve** can assist the **operator** in detecting abnormal operation.

Check compliance by the methods described to B.3.1 and Clause 7.

6.1.2 Cleaning, and sterilization or disinfection

All parts and **accessories** indicated for reuse in the **accompanying documents**, which can be contaminated by exhaled **patient** gas during **normal use** and during the **single fault condition** simulated in B.3.10, shall be capable of being cleaned, and sterilized or disinfected.

Parts and **accessories** labelled as capable of being sterilized shall be accompanied with information according to ISO 17664.

Check compliance by inspection.

6.1.3 * Functional test after reassembly

6.1.3.1 Reassembly

A **resuscitator** intended to be dismantled by the **operator** (e.g. for cleaning) shall be designed to minimize the risk of incorrect reassembly when using only items supplied with the **resuscitator set**.

Check compliance by inspection.

6.1.3.2 Functional test

The **accompanying documents** shall indicate a functional test procedure that can be carried out by the **operator** after reassembly, using only items supplied with the **resuscitator set,** which demonstrates that the **resuscitator** has been properly reassembled.

Check compliance by the method described in B.3.2.

6.1.4 Flow-direction-sensitive component connectors

Any **operator**-detachable, **flow-direction-sensitive component** shall be so designed that it cannot be fitted in such a way as to present a **safety hazard** to the **patient**.

Check compliance by inspection.

6.2 Resistance to environmental influences

6.2.1 * Storage and operating conditions

6.2.1.1 Storage

The **resuscitator** and the **resuscitator set** shall, after storage at a temperature between –40 °C and +60 °C and at any relative humidity between 40 % and 95 %, comply with the requirements of 5.1.10, 7.2.2, 7.2.4 and 7.2.6.

Check compliance by the method described in B.3.3.

6.2.1.2 Operating conditions

The **resuscitator** and the **resuscitator set** shall comply with the requirements of 5.1.10, 7.2.2, 7.2.4 and 7.2.6 throughout the range of relative humidity from 5 % to 95 % either:

— throughout the temperature range from –18 °C to +50 °C, or

— if an extended operating range is given [see 8.3.2.4 i)], throughout the temperature range indicated in the **accompanying documents.**

Check compliance by the method described in B.3.3.

6.3 Resistance to typical use

6.3.1 Mechanical shock

6.3.1.1 * Drop test

The **resuscitator** shall continue to function within the tolerances indicated for **normal use** following the drop test for the **resuscitator set** and the drop test for the removable parts, as described in B.3.4.

Check compliance by the method described in B.3.4.

6.3.2 Splash proof

The **resuscitator** shall be splash proof, classified as IPX4 in IEC 60529.

During and after the test specified in IEC 60529, the **resuscitator**, under the least favourable working conditions but in accordance with the **accompanying documents**, shall continue to function within the tolerances indicated for **normal use** and shall not cause a **safety hazard**.

Check compliance by inspection and by application of the requirements of IEC 60529.

6.3.3 * Immersion in water

After immersion in water by the method described in B.3.5, the **resuscitator** shall continue to function within the tolerances indicated for **normal use**.

Check compliance by the method described in B.3.5.

6.4 Size and mass

6.4.1 * Size

The **resuscitator set** provided or recommended in the **accompanying documents** shall pass through a 300 mm by 600 mm rectangular opening.

Check compliance by inspection.

6.4.2 * Mass

The mass of the **resuscitator set** with all recommended contents (including any full gas cylinders) shall not exceed 5 kg.

The part of the **resuscitator** incorporating the **patient connection port** shall weigh less than 0,3 kg.

Check compliance by inspection.

6.5 Gas supply

6.5.1 Gas cylinders and cylinder valve

The identification of the contents of the gas cylinder supplied or recommended in the **accompanying documents** shall be in accordance with ISO 32.

The gas cylinder valve fitted to the gas cylinder supplied or recommended in the **accompanying documents** shall meet the requirements given in ISO 10297. Small cylinders with special fittings may sometimes used in special situations.

Check compliance by inspection.

6.5.2 Captive cylinder valve key

If detachable, the hand wheel, key or other part for opening the cylinder valve shall be made captive by means of a retaining chain or similar attachment capable of withstanding a static load of not less than 200 N (20 kg) without breaking.

Check compliance by inspection.

6.5.3 Cylinder regulator

The pressure regulator supplied or recommended in the **accompanying documents**, as part of the **resuscitator set** medical gas supply system (see 5.1.11), shall meet the requirements given in ISO 10524-1 or ISO 10524-3 as appropriate to the type of cylinder supplied or recommended.

Check compliance by inspection.

6.5.4 External supply

If the **resuscitator** is provided with a probe (see 5.2.1) for connection by the **operator** to a medical gas supply system (e.g. a pressure regulator complying with the ISO 10524 series, or a terminal outlet in an ambulance), it shall operate and meet the requirements of this part of ISO 10651 for a pneumatic power supply throughout the range of 280 kPa to 600 kPa and shall cause no **safety hazard** under the **single fault condition** of the medical gas supply of up to 1 000 kPa inlet pressure.

Check compliance by functional testing.

6.5.5 Permanently connected resuscitator

If the **resuscitator** is not supplied with a probe for connection by the **operator** to a medical gas supply system, it shall operate and meet the requirements of this part of ISO 10651 throughout the **rated** range of gas cylinder contents indicated in the **accompanying documents** and shall cause no **safety hazard** under the **single fault condition** of the cylinder pressure regulator supplying up to 1 000 kPa inlet pressure.

Check compliance by functional testing.

6.5.6 * Intermediate hose

Any **intermediate hose** between parts of the **resuscitator** that can be **operator** connected shall not be fitted with connectors that are interchangeable with the connectors on hoses conforming to ISO 5359 and shall not allow parts of the **resuscitator** to be incorrectly connected.

Check compliance by inspection.

6.5.7 Gas container capacity

Any **resuscitator set** supplied or recommended in the **accompanying documents** shall have provision to accommodate one or more gas cylinders that provide the gas source in the medical gas supply system. **Resuscitator sets** shall contain sufficient gas to enable the **resuscitator** to deliver to the **patient** at least 100 l of gas with an O_2 concentration $>$ 85 % volume fraction, when tested as described in B.3.6.

Check compliance by the method described in B.3.6.

7 Performance

7.1 Ventilatory requirements

7.1.1 * Delivered oxygen concentration

The **resuscitator** shall deliver an oxygen concentration of at least 85 % volume fraction.

Check compliance by the method described in B.3.7.

7.1.2 * Resistance to spontaneous breathing

7.1.2.1 General

Attachable **accessories** or selectable functions that are provided for temporary use for specific purposes, but which increase the inspiratory and expiratory resistance when in use, are not used during the tests for compliance to the following requirements if they are indicated in the **accompanying documents** in a warning as required by 8.3.2.3 d).

Check compliance by inspection.

7.1.2.2 Inspiratory resistance during the resuscitator expiratory phase

During the **expiratory phase**, the pressure at the **patient connection port** shall not exceed 6 hPa (6 cm H_2O) below atmospheric pressure at an inspiratory airflow of 60 l/min for **resuscitators** intended for **patients** with a body mass greater than 10 kg and of 6 l/min for **resuscitators** intended for **patients** with a body mass up to 10 kg.

Check compliance by the method described in B.3.8.1.

7.1.2.3 Spontaneous breathing with the gas input pressure outside the rated range

When operating with the gas input pressure outside the **rated** range and during the **inspiratory phase**, either the **resuscitator** shall generate a **delivered volume** and **inspiratory time** within ± 25 % of that achieved during **normal use,** or the **resuscitator** shall be designed to allow spontaneous breathing.

Under these spontaneous breathing conditions, the pressures below and above atmospheric pressure at the **patient connection port** shall not exceed 6 hPa (6 cm H_2O), at airflows of 30 l/min for **resuscitators** intended for **patients** with a body mass greater than 10 kg and of 3 l/min for **resuscitators** intended for **patients** with a body mass up to 10 kg.

EXAMPLE 1 The inlet pressure falls below the minimum **rated** operating pressure of the **resuscitator**, e.g. as the content of the cylinder becomes depleted.

EXAMPLE 2 The inlet pressure exceeds the maximum **rated** operating pressure of the **resuscitator**, e.g. when the regulator fails.

Check compliance by the method described in B.3.8.2.

7.1.2.4 Expiratory resistance

In the absence of a removable positive end-expiratory pressure (PEEP) valve or with an integral positive end-expiratory pressure function set to its minimum value, the pressure at the **patient connection port** during the **expiratory phase** shall not exceed 6 hPa (6 cm H_2O) above atmospheric pressure at an expiratory airflow of 60 l/min for **resuscitators** intended for **patients** with a body mass greater than 10 kg and of 6 l/min for **resuscitators** intended for **patients** with a body mass up to 10 kg. (See also 8.3.2.2 h.)

Check compliance by the method described in B.3.8.3.

7.1.3 * Inadvertent PEEP

The positive expiratory pressure at the end of the **expiratory phase** shall not exceed 2 hPa (2 cm H_2O).

Check compliance by the method described in B.3.9.

7.1.4 * Inadvertent continuing expiratory pressure

Means shall be provided to prevent the build-up of continuing positive pressure from exceeding 2 hPa (2 cm H_2O).

Check compliance by the method described in B.3.10.

7.1.5 * Resuscitator dead space and dead space of airway accessories

The **resuscitator dead space** shall not exceed 5,5 % of the minimum **delivered volume** from the **resuscitator**.

The dead space of any combination of **accessories** recommended for attachment to the **resuscitator** (e.g. mask, filter, artificial airway), together with the **resuscitator dead space**, shall not exceed 100 ml for **resuscitators** delivering more than 300 ml. For **resuscitators** delivering 300 ml or less, this dead space shall not exceed 30 % of the minimum **delivered volume**, as indicated in the instructions for use.

Check compliance by physical measurement or by measurement with water.

7.2 * Ventilation performance

7.2.1 General

All tests in this part of ISO 10651 shall be performed when only one **operator** uses the **resuscitator**.

Resuscitators shall meet the requirements of 7.2 according to their classification as one or more of the following.

7.2.1.1 Manually-cycled resuscitator

A **manually-cycled resuscitator** shall meet the requirements specified in 7.2.2 to 7.2.8.

7.2.1.2 Automatic pressure-cycled resuscitator

An **automatic pressure-cycled resuscitator** shall meet the requirements specified in 7.2.2 to 7.2.7.

7.2.1.3 Automatic time-cycled or volume-cycled resuscitator

An **automatic time-cycled** or **automatic volume-cycled resuscitator** shall meet the requirements specified in 7.2.2 to 7.2.7.

7.2.1.4 Resuscitator with patient-triggering

A **resuscitator** with **patient-triggering** shall meet the requirements specified in 7.2.10 in addition to the requirements for the associated automatic **resuscitator** function.

7.2.1.5 Resuscitator with demand valve

A **resuscitator** with a **demand valve**, as an integral part, shall meet the requirements specified in 7.2.9 in addition to the requirements for the associated **resuscitator** function.

7.2.2 * Delivered volume (V_{del})

The **resuscitator** shall deliver the **delivered volume** specified for its body mass designation, as shown in Table 1, using the given values for compliance and resistance and, where independently adjustable, the **inspiratory/expiratory time** ratio and frequency. The **delivered volume** range of any **resuscitator** with **operator-**adjustable **delivered volume** shall encompass the values specified for the limits of their body mass range (as indicated in the **accompanying documents**), in the same manner as the specific designation range examples listed.

Check compliance by the method described in B.3.11.

Table 1 — Delivered volume requirements and test conditions

Parameter		Test conditions		
Compliance (l/hPa)		0,001	0,01	0,02
Resistance [hPa/(l/s)]		200	20	20
Inspiration/expiration time ratio [a] ± 20 %		1:1	1:2	1:2
Frequency [a] (breaths/min)		60 ± 6	20 ± 2	12 ± 1
Typical descriptive designation (if used)	**Designated body mass or range**	**Delivered volume requirement for the given test conditions** ml		
Adult with preset volume	m [b] $\geqslant$ 40 kg	—	—	$V_{del} \geqslant 600$
Adult with adjustable volume	$m_{max} \geqslant$ 40 kg m_{min} [c]	—	$V_{del} < 7 \times m_{min}$	$V_{del} > 600$
Adult/ child	$m_{max} \geqslant$ 40 kg m_{min} [c]	—	$V_{del} < 7 \times m_{max}$	$V_{del} > 600$
Neonatal/child	m_{max} m_{min} [c] $\leqslant$ 5 kg	$V_{del} < 20$	$V_{del} > 15 \times m_{min}$	—
Neonatal	$m \leqslant$ 5 kg	$V_{del} \leqslant 20$	—	—

[a] This setting is only applicable to **resuscitators** that allow this parameter to be set independently of **delivered volume**.

[b] m = body mass, expressed in kilograms, as indicated in the instructions for use.

[c] Where a body mass range is indicated in the instructions for use, m_{min} is the minimum body mass and m_{max} is the maximum body mass. See also 8.3.2.2 a).

7.2.3 * Consistency of delivered volume

If the **resuscitator** is intended for use with **patients** of body mass $m > 40$ kg, then, when the resuscitator is set to deliver > 85 % volume fraction of O_2 for each cycle and the compliance and resistance are changed as specified in B.3.12 (with no change to the **resuscitator** settings or rate of manual triggering if the **delivered volume** is not controlled automatically), the **delivered volume** to a test lung shall not deviate by more than ± 150 ml.

Check compliance by the method described in B.3.12.

7.2.4 Pressure limitation under normal use

The pressure at the **patient connection port** shall not exceed 60 hPa (60 cm H_2O) during **normal use.** A setting for the **pressure-limiting device** higher than 60 hPa may be made available for certain **patients**, although the selection of such a setting requires medical advice.

Check compliance by the method described in B.3.13.

7.2.5 Pressure limitations under single fault condition

The maximum achievable pressure at the **patient connection port** under **single fault condition** shall not exceed 80 hPa (80 cm H_2O).

*Check compliance by the method described in B.3.13, while simulating relevant **single fault conditions**.*

7.2.6 * Pressure-limitation activation alarm signal

A means to detect operation of the **pressure-limiting device** required in 7.2.4 (7.2.5 for pressure-triggered **resuscitators**) shall be provided. It shall activate an auditory signal to indicate loss of **delivered volume** due to the action of the **pressure-limiting device**, or when the set inspiratory pressure limitation level is reached.

It shall not be possible to set the inspiratory pressure alarm limit above the maximum pressure permitted by the means of pressure limitation referred to in 7.2.4 (7.2.5 for pressure-triggered **resuscitators**).

NOTE Transient **patient**-generated pressures (e.g. a cough) might not activate the signal.

Check compliance by occlusion of the ***patient connection port*** *and controlled ventilation of the test lung as described in B.3.13.*

7.2.7 * Inspiratory flow

A **resuscitator** with a preset flow, intended for use with **patients** with greater than 40 kg body mass (adult use), when set to deliver > 85 % O_2, shall deliver inspiratory flows between 25 l/min and 40 l/min, both on free flow to atmosphere and against a back-pressure of 20 hPa (20 cm H_2O). Such **resuscitators** with **operator-**adjustable flows shall have a range of adjustment that overlaps this range.

Check compliance by the method described in B.3.14.

7.2.8 Operation of manual trigger on a manually-cycled resuscitator

If a means is provided on the **resuscitator** for manual-cycling, it shall be possible for the **operator** (a normal adult rescuer) to operate the function with one finger whilst maintaining a mask seal using the two handed head-tilt, chin-lift method recommended by international resuscitation guidelines [15] [16].

Check compliance by the method described in B.3.15.

7.2.9 Demand valve

7.2.9.1 General

The requirements in 7.2.9.2 to 7.2.9.4 apply only to a **demand valve** included as an integral part of the **resuscitator**, if provided.

7.2.9.2 Threshold pressure for initiation of flow

The pressure at the **patient connection port** needed to initiate gas flow from the **demand valve** shall not be numerically greater than 2 hPa (2 cm H_2O) below atmospheric pressure.

Check compliance by functional test using the method described in B.3.16.

7.2.9.3 Peak inspiratory flow

The minimum peak inspiratory flow shall be 100 l/min for at least 2 s, with a pressure at the **patient connection port** not numerically greater than 8 hPa (8 cm H_2O) below atmospheric pressure. This flow shall be attained within 250 ms.

Check compliance by functional test using the method described in B.3.16.

7.2.9.4 Termination pressure

Demand flow shall have terminated either when the pressure at the **patient connection port** equals atmospheric pressure or at the positive pressure stated in the **accompanying documents.** See also 8.3.2.2 q).

Check compliance by functional test using the method described in B.3.16.

7.2.10 * Patient-triggered resuscitator

If the **accompanying documents** state that the **resuscitator**, or a function of the **resuscitator**, is capable of being **patient-triggered,** then the trigger shall operate within 250 ms when the pressure at the **patient connection port** is reduced to not numerically greater than 2,5 hPa (2,5 cm H_2O) below atmospheric pressure.

Check compliance by the method described in B.3.17.

8 Identification, marking and documents

8.1 General

8.1.1 Conditions

All parameters shall be expressed under ATPD (atmospheric temperature and pressure, dry) conditions.

8.1.2 Units of measure

Numeric indications of parameters on **resuscitators** shall be expressed in SI units in accordance with ISO 31 (all parts) except the quantities listed in Table 2, which are not SI units but may be expressed in the indicated units.

Table 2 — Non-SI units of pressure that may be used on resuscitators

Name	Symbol
Millimetres of mercury	mm Hg
Centimetres of water	cm H_2O
Bar	bar
Millibar	mbar

For consistency in international documents, only the symbol “l” is used for litre, although the symbol “L” is also given in ISO 1000.

For application of SI units, their multiples and certain other units, ISO 1000 is applicable.

Check compliance by inspection.

8.2 Marking

8.2.1 * Legibility of markings

All markings and visual indicators relating to the application, function and operation of the **resuscitator set** shall be **clearly legible** when viewed from the intended position of the **operator** for the related function being performed.

Check compliance by the following test.

*Position the **resuscitator set** or its parts so that the viewpoint is the intended position of the **operator**; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 0,8 m. The ambient illuminance is the least favourable level in the range of 100 lx to 1 500 lx. The observer has a visual acuity of 0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), corrected if necessary.*

The observer correctly reads the marking from the viewpoint.

8.2.2 * Durability of markings

The markings required by this clause shall be removable only with a tool and sufficiently durable to remain **clearly legible** during the maximum expected product service life as defined by the manufacturer of the **resuscitator**. In considering the durability of the markings, the effect of **normal use** shall be taken into account.

Check compliance by inspection and the following tests.

a) Markings shall be **clearly legible** after all the tests of this part of ISO 10651 have been performed. Adhesive labels shall not have worked loose or become curled at the edges.

b) *For markings required by this subclause, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit and then for 15 s with a cloth rag soaked with isopropanol.*

8.2.3 Identification

Resuscitators and their detachable components and **accessories** shall be marked with:

— the name or trade-mark of the manufacturer or authorized representative, if applicable,

— a model or type reference,

— a serial (or Symbol 3.16 from ISO 15223:2000) or lot or batch (or Symbol 3.14 from ISO 15223:2000) identifying number, and

— the year of manufacture (or Symbol 3.13 from ISO 15223:2000) or use by date (or Symbol 3.12 from ISO 15223:2000).

Check compliance by inspection.

8.2.4 Controls and indicators

All controls and indicators on the **resuscitator** shall be clearly identified. Figures, letters or other visual means shall indicate different positions of controls or switches. Controls that increase or decrease a function shall be marked with an indication to inform the **operator** which action is required to increase or decrease the controlled function.

Check compliance by inspection.

8.2.5 Indication of pressure-limiting device setting

If the **resuscitator** is supplied with a **pressure-limiting device** set at one fixed pressure, the **nominal** pressure setting at which the system activates shall be clearly marked on the **resuscitator**.

Check compliance by inspection.

8.2.6 Indication of use of function affecting performance

Any ancillary function selection made available to the **operator** in order to protect or provide treatment for the **patient** in specific emergencies, but which affects the normal performance of the **resuscitator** (e.g. an anti-inhalation valve for use in contaminated atmospheres), shall be clearly marked in a manner that makes the **operator** aware that it is in use.

Check compliance by inspection.

8.2.7 Indication of pneumatic power rating

The pneumatic power requirements of the **resuscitator** shall be marked. As a minimum requirement, this shall be the maximum flow that a gas supply pressure regulator is required to supply while maintaining the pressures stated in 6.5.4.

Check compliance by inspection.

8.2.8 Flow-direction-sensitive component

Any **flow-direction-sensitive component** connections shall be marked with the appropriate flow direction on the component.

Check compliance by inspection.

8.2.9 Indication of latex

If applicable, a warning shall be given that latex is used.

Check compliance by inspection.

8.2.10 Indication of protection against water ingress

The **resuscitator** shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the degree of protection provided by the enclosure with respect to harmful ingress of particulate matter and water. See also 6.3.2.

The minimum requirement of this part of ISO 10651 is IPX4.

Check compliance by inspection.

8.3 Information provided by the manufacturer for operation and maintenance

8.3.1 General

The manufacturer shall provide **accompanying documents** that include instructions for use and maintenance of the **resuscitator** and its recommended **accessories**. The size and shape of these **accompanying documents** shall be such that they can be enclosed with or attached to the container of the **resuscitator set**.

*Check compliance by inspection of the **accompanying documents**.*

8.3.2 Contents

The **accompanying documents** shall include the following:

8.3.2.1 Operational instructions and information, including where applicable:

a) any instructions on how to make the **resuscitator** operational in all intended modes of operation, including the specifications of any recommended, but not supplied, **accessories** (e.g. gas cylinder, see 6.5.1) necessary for the **resuscitator set** to conform to this part of ISO 10651 (see 5.1.11);

b) * a method of testing the **pressure-limitation device** (see 7.2.4 or 7.2.5, as applicable) and its associated alarm system prior to connection of the **resuscitator breathing system** to the **patient**;

c) a method of testing any other alarm systems, if provided, before use or at recommended intervals;

d) the intended use of the **resuscitator** (e.g. for adult, paediatric or neonatal **patients**, suitability for any special environments, intended **operator** skill level);

e) an explanation of the meanings of the symbols used for marking;

f) the **resuscitator** model or type reference to which the **accompanying documents** are applicable;

g) the name or trademark of the manufacturer or authorized representative, and an address to which the organization responsible can refer.

Check compliance by inspection of the ***accompanying documents****.*

8.3.2.2 Performance information shall be disclosed, including where applicable:

a) the body mass range for which the **resuscitator** is suitable (this may be expressed as a body weight range);

b) the delivered oxygen concentration and the conditions that affect this parameter;

c) the delivered volume range;

d) the **resuscitator** cycling frequency range;

e) the cycling pressure range;

f) the inspiratory flow and **inspiratory time** ranges;

g) the **resuscitator dead space**, and the total dead space with and without recommended **accessories**;

h) the expiratory resistance and inspiratory resistance as measured using test method B.3.8.1 and B.3.8.3, and the resistance imposed by any recommended **accessory**;

i) any details of the **pressure-limiting device** and override mechanism operation, if any;

j) the range of gas supply pressure and flow requirements for the **resuscitator** and, if provided, the **demand valve**;

k) the functional characteristics or manufacturer's identification of **operator**-detachable, **resuscitator breathing system** components, including any **breathing system filter** fitted or recommended;

l) the accuracy of any specified ventilation parameters and the range and accuracy of any controls or indicators supplied on the **resuscitator** or on **accessories** supplied for use with the **resuscitator**. The accuracies of indicators should be expressed in the form of the maximum zero error (bias) quoted in appropriate units plus a sensitivity error quoted, e.g. as a percentage of the reading;

m) the interdependence of controls, if applicable;

n) a description of how the **delivered volume** or **minute volume** and oxygen concentrations are affected by pressure at the **patient connection port**, in particular the maximum deviations from the calibrated or stated settings of these parameters at mean pressures of 5 hPa, 15 hPa, 30 hPa and 60 hPa (5 cm H_2O, 15 cm H_2O, 30 cm H_2O and 60 cm H_2O);

o) the approximate duration of the gas supply, supplied or recommended, when operated with disclosed typical **resuscitator** settings;

p) the approximate duration of the gas supply, expressed as time per litre of the volume of the cylinder when charged at a disclosed typical **nominal** pressure and when operated with disclosed typical **resuscitator** settings (this figure allows for the comparison between different **resuscitators** for gas usage efficiency);

q) for **patient demand valves**, the pressure for termination of flow, if positive.

Check compliance by inspection of the ***accompanying documents****.*

8.3.2.3 Appropriate warnings, including where applicable:

a) a statement to the effect that this resuscitator is intended for first responders to a breathing emergency only and that patients must be transferred to a transport and emergency ventilator, conforming to ISO 10651-3, as soon as such equipment becomes available;

b) a warning to the effect that incorrect operation of the resuscitator can be hazardous;

c) any guidance regarding use in hazardous or explosive atmospheres, including a warning that if the resuscitator entrains or permits the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous unless entrainment is prevented or appropriate filtration is provided. If applicable, a description is provided of how to prevent such entrainment or inhalation, e.g. by the use of an anti-inhalation valve, or of how a filter can be fitted;

d) if a part which can be temporarily fitted or selected, to filter or prevent the entrainment of a contaminated atmosphere, affects the resuscitator performance as required by this part of ISO 10651, a warning that such part is only to be used when essential and must be removed for all other uses as well as a statement that there are increased risks associated with its use;

e) any warnings that in the presence of high oxygen concentrations there is danger from smoking or naked flames and that oil or grease should not be used on the resuscitator or any parts of the resuscitator set;

f) if a pressure-limitation override is provided, a warning that it must only be used under medical supervision;

g) a recommendation that users should refer to ILCOR / AHA / ERC guidelines [16] to determine the suitability of different types of resuscitator for use in **cardiopulmonary resuscitation**;

h) a statement that this resuscitator is not to be used on unattended patients;

i) a recommendation that an alternative means of ventilation should be available (e.g. that training should include mouth to mouth ventilation, with or without a protective barrier);

j) if needed in order to satisfy the requirements of 6.1.2, a statement that a **breathing system filter** is necessary to prevent cross-contamination of parts of the **resuscitator** that cannot be disassembled for cleaning and disinfection, or for cleaning and sterilization.

Check compliance by inspection of the ***accompanying documents****.*

8.3.2.4 General information, including where applicable:

a) the external dimensions of the **resuscitator** and the carrying case or frame of the **resuscitator set**;

b) the mass of the **resuscitator** and the supplied or recommended **resuscitator set**, including all associated items (e.g. cylinders, regulators, carrying casing) required to conform to this part of ISO 10651;

c) a statement that subatmospheric pressure is present in the **expiratory phase**;

d) for triggered **resuscitators**, a technical description of the means of triggering;

e) for **resuscitators** that are intended to interact with any breathing effort by the **patient** [e.g. synchronized intermittent mandatory ventilation (SIMV)], a quantitative description of the algorithm used;

f) the threshold criteria, including the pressure level, if the **resuscitator** is claimed to be responsive in any way to a **patient's** breathing effort, e.g. through inhibition of ventilation or the initiation of inspiration with a breathing effort greater than that permitted for triggering (see 7.2.10);

g) the purpose, type, range and sensing position of all measuring and display parts, either incorporated into the **resuscitator** or recommended for use with the **resuscitator**;

h) for any alarm systems on the **resuscitator**, a statement of their type, capabilities, principle of alarm detection, period of alarm signal generation;

i) any operational environmental limits;

j) any storage environmental limits.

Check compliance by inspection of the ***accompanying documents****.*

8.3.2.5 Maintenance information, including where applicable:

a) any instructions for the dismantling and reassembly of components requiring cleaning (including clearing of any vomitus), and disinfection or sterilization, and details of a functional test of operation to be carried out after reassembly and before use (see 6.1.3.2);

b) any recommended methods of cleaning and disinfection, or of cleaning and sterilization, of the **resuscitator**, its components and its **accessories**;

c) a diagram of the pneumatic system of the **resuscitator** and a diagram of any **resuscitator breathing system,** either supplied or recommended;

d) a list of **operator**-replaceable parts;

e) any maintenance requirements.

Check compliance by inspection of the ***accompanying documents****.*

Annex A
(informative)

Rationale

This annex provides a rationale for some requirements of this part of ISO 10651, and is intended for those who are familiar with the subject of this part of ISO 10651 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 10651 necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 10651. The numbering is, therefore, not consecutive.

A.1 Scope

Internationally agreed guidelines for **cardiopulmonary resuscitation** are published by national and international organizations, e.g. AHA, ILCOR, ERC [16]. These guidelines have been considered in the preparation of this part of ISO 10651. However, the objective of this part of ISO 10651 is to address issues concerning **patient** safety and not to make recommendations for clinical practice that are inevitably continuously evolving. Therefore, the requirements of this part of ISO 10651 do not limit the design of **resuscitators** to adapt them for use in conjunction with any particular guidelines.

A.3.7 Delivered volume

Ventilation and resuscitation guidelines give guidance concerning lung inflation in terms of tidal volume; which is defined as “the volume of gas entering or leaving the **patient** or the lung model during the **inspiratory phase**”. It has been common practice to specify and calibrate the performance of **resuscitators** using this term but, in reality, without the use of techniques such as exhaled volume measurement, the **resuscitator** can only generate a known volume. A proportion of this volume might not enter the **patient's** lung due to leakage at the connection to the **patient's** airway e.g., mask leakage. The term **delivered volume** is used in this part of ISO 10651 in reference to the volume output of the **resuscitator** in order to avoid ambiguity. In the absence of leaks, the **tidal volume** the **patient** receives will be the **delivered volume** that the **resuscitator** delivers.

A.5.1.6 Breathing system filter

Resuscitators with their operating mechanisms close to the **patient connection port** are vulnerable to expired gases entering parts of the **resuscitator** which cannot be cleaned, due to the **single fault condition** of back leakage through the **patient valve**, such that cross-contamination of inspired gases can occur. It is therefore necessary that either an effective **breathing system filter** is used to filter expired/inspired gases or that the parts can be cleaned and disinfected or sterilized. A **breathing system filter** not conforming to ISO 23328-1 is unlikely to be effective for this purpose.

A.5.1.11 Resuscitator set

Resuscitators are intended for use as part of a **resuscitator set** that will enable them to be carried rapidly to the **patient** requiring ventilation. They are dependent upon the accompanying gas cylinder for their power, but if the cylinder is too heavy, **operators** will be discouraged from using the **equipment** in first response situations. It is considered that the ability to supply high oxygen concentrations (e.g. > 85 % volume fraction) at a minimum **minute volume** of 10 l for 10 min is a minimum requirement for the **resuscitator set** (see 7.5.7) whilst not involving excessive mass (see 6.4.2). It should provide time for initial resuscitation while backup resources are being organized.

A.5.2.5 Gas exhaust port connector

The **exhaust port** connection described is often used for the connection of **accessories** such as a PEEP valve. It is essential that breathing system conical connectors are not compatible with this port. It is also

important that the **exhaust port** be designed in such a way that it cannot be confused with the **patient connection port** during use of the **resuscitator**.

A.6.1.1 Patient valve function after contamination with vomitus

It is important that vomitus can be cleared quickly and effectively from a **resuscitator** so that resuscitation can be continued with a minimum of interruption.

A.6.1.3 Functional test after reassembly

Reassembling a **resuscitator** incorrectly, so that it does not function properly or causes complete malfunction, can result in a serious **safety hazard** such as over pressurization of the **patient** or inadequate ventilation of the **patient**. The intention of these requirements is that both the **resuscitator** design and the functional test should have the objective of minimizing the possibility of an incorrectly reassembled or incorrectly prepared **resuscitator** being used on a **patient**.

A.6.2.1 Storage and operating conditions

Resuscitators can be expected to be exposed to the environmental extremes outlined in 6.2.1, since such extremes are often reached throughout the world in places where **resuscitators** are used and **users** should expect to be able to use them without question. If **accompanying documents** claim a wider range of environmental tolerance, this claim is required to be validated.

Although **resuscitators** are designed in a manner that allows them to be used in very dry conditions, no test is specified because the type of **equipment**, which comes within the scope of this part of ISO 10651, is thought unlikely to have its performance affected by very dry ambient conditions. Testing at two levels of low humidity for both short and long term and at both high and low temperatures would considerably extend the testing required with little perceived benefit. A single short-term test at high humidity and high temperature has been included but this will not expose susceptibility to such problems as corrosion or mould growth. It is expected, therefore, that the manufacturer will perform a failure analysis to establish the possible effects of both the lowest and highest humidity specified.

A.6.3.1.1 Drop test

It is important that **resuscitators** can withstand the severe shock caused by falls from ambulances, hospital beds, etc.

A.6.3.3 Immersion in water

Resuscitators are often used in areas where they might be accidentally dropped into water during the resuscitation. If the **resuscitator** is recovered quickly from the water, it should still function correctly.

A.6.4.1 Size

Resuscitators will often need to be used in situations with poor access. The dimensions specified will enable the **resuscitator set** to be passed through a standard manhole entrance.

A.6.4.2 Mass

See also A.5.1.11.

Resuscitators are often packaged as a single entity incorporating both the control system and the **patient valve**. There is a consensus [15] [17] that the mass of any **resuscitator** connected directly to a mask or an airway should be sufficiently lightweight that it does not become difficult to keep in place, or cause a disconnection or extubation, when being used in a vehicle traversing rough terrain. This can be the case in the use of **resuscitators** during the initial stages of a rescue.

A.6.5.6 Intermediate hose

If the **resuscitator** uses more than one hose, it is important that the hoses cannot be wrongly connected. If the supply hose is **operator**-detachable, it should have standard connectors. If an **intermediate hose** is also

used, these connectors have the possibility for the **operator** to accidentally connect a hose end to the wrong connector.

A.7.1.1 Delivered oxygen concentration

All resuscitation guidelines advocate the use of 90 % to 100 % oxygen volume fraction, wherever possible, in the initial stages of resuscitation. As the **resuscitators** covered by this part of ISO 10651 are oxygen-powered there is no justification for not delivering high concentrations in at least one of the modes of operation.

A minimum of 85 % O_2 volume fraction has been used because this allows minor entrainment leaks to occur and it is considered that only below this concentration will the reduction be significant in terms of benefit to **patient** oxygenation.

On **resuscitators** that allow the selection of other oxygen concentrations, entrainment devices are often used. These devices can be of benefit in extended rescues by decreasing the consumption of cylinder oxygen but for safe use under all conditions it is essential that the **operator** is made aware of any resultant compromises in performance [see 8.3.2.2 n)].

A.7.1.2 Resistance to spontaneous breathing

To facilitate full exhalation in a minimum time, expiratory resistance should be as low as possible. It is also important that any spontaneous respiratory efforts by the **patient** are not impeded, particularly if the ventilation is inadequate. The design of a **resuscitator** should be such that it is possible for the **patient** to breathe spontaneously without excessive sub-atmospheric pressure when the **resuscitator** is applied to the **patient's** airway, but is not delivering flow to the **patient** (i.e., during the **expiratory phase**).

Additionally, if the **operator** does not respond immediately to a low supply gas condition, the **resuscitator** should not impede any spontaneous breathing effort of the **patient** in the event of inadequate ventilation. Therefore, the **patient** needs to be able to breathe during the **expiratory phase** and during the **inspiratory phase** if this phase lengthens, or the **delivered volume** decreases, unacceptably. For this reason, maximum values for expiratory and inspiratory resistance under these conditions have been specified.

A.7.1.3 Inadvertent PEEP

Certain **resuscitator** designs do not allow the **patient** to fully exhale due to the mechanism used, resulting in a basic PEEP level that cannot be avoided. This effect needs to be strictly limited in **resuscitators** used in **cardiopulmonary resuscitation** because the resultant increased mean intra-thoracic pressure can impede venous return in this application.

A.7.1.4 Inadvertent continuing expiratory pressure

Most **resuscitators** of the type covered by this part of ISO 10651 use an inspiratory valve made of elastomeric materials. Inappropriate handling, contamination or variability of the manufacturing process can all result in imperfect sealing of this valve. Unless the **resuscitator** is specifically designed to accept a reasonable level of back leakage, it is possible for pressure balance to occur such that the **patient** cannot exhale. Preventing the **patient** from exhaling can quickly lead to a potentially lethal situation. The test specified is designed to ascertain that such back-leakage will not cause the valve to malfunction in this manner.

A.7.1.5 Resuscitator dead space and dead space of airway accessories

It is important to minimize apparatus dead space in order to limit rebreathing of expired gases. The maximum values specified are higher than the desirable values but are inevitable if a heat and moisture exchanger (HME) or **breathing system filter** of sufficiently low resistance is specified. At the adult **delivered volume** of 600 ml, the allowed percentage is $<$ 17 %. **Resuscitators** suitable for children are invariably adjustable and so where a **delivered volume** below 300 ml is required, it is possible to increase the **delivered volume** to compensate for the rebreathing.

With respect to the measurement of the dead space, although only an approximation, the physical measurement of the volume shared by the inspired and expired gases is used. This is considered sufficiently accurate for a disclosure for this type of **equipment**. If it is considered that for a particular design this method is not appropriate, a specific test should be used.

A.7.2 Ventilation performance

Many **resuscitators** of the type covered by this part of ISO 10651 have more than one mode of operation, e.g. a **demand valve** with a manual trigger, an automatic **resuscitator** with a selectable manual mode of operation or an **automatic time-cycled resuscitator** with **patient-triggering**. Each mode of operation has to satisfy its own set of requirements as specified in this part of ISO 10651.

A.7.2.2 Delivered volume (V_{del})

The required **delivered volume** values given in Table 1 take account of general ventilation guidelines that indicate tidal volumes of 10 ml/kg to 15 ml/kg, and also the more recent recommendations by ILCOR and AHA to use a reduced tidal volume of 6 ml/kg to 7 ml/kg during pulmonary resuscitation in order to minimize gastric inflation.

To ensure that adequate tidal volumes can be achieved, even with some mask leakage and with adverse lung characteristics, the higher value of $15 \times m$ (m = body mass) has been used to ensure that **patients** are not under-inflated at the maximum setting of variable output child **resuscitators**.

7 ml/kg has been used as the maximum **delivered volume** in determining the suitability of a **resuscitator** to ensure that small **patients** are not over-inflated. **Resuscitators** suitable for children will, inevitably, be adjustable and with the use of this figure a volume of 10 ml/kg to 15 ml/kg can still be delivered if necessary for correct ventilation.

The **delivered volume** requirement of 600 ml for adults is still within the recommended target range for adult **cardiopulmonary resuscitation** but has a margin for mask leakage even for a small, 40 kg adult.

The ventilatory frequencies specified also follow current recommendations for **cardiopulmonary resuscitation**.

A.7.2.3 Consistency of delivered volume

When a **resuscitator** is used to ventilate a cardiac arrest victim, it will invariably be ventilating a lung with rapidly changing compliance and resistance. For optimum **cardiopulmonary resuscitation** it is important that the **delivered volume** and the **inspiratory time** and **expiratory time** are consistently maintained and not affected by the changes in lung characteristics.

In particular, pressure-cycled **resuscitators** will vary the **delivered volume** and the **inspiratory time** and **expiratory time** in order to achieve the selected pressure level. This is one of the main reasons why they are not preferred for use during **cardiopulmonary resuscitation** by lay **operators**. Unless their function is modified to overcome this variability, **resuscitators** operating on this principle will not meet the performance requirements of this part of ISO 10651.

Only the high oxygen concentration mode is used during these tests, because this is the mode that is recommended during the critical phase of the rescue.

A.7.2.6 Pressure-limitation activation alarm signal

This alarm signal serves not only to indicate that the set pressure level has been reached but also when gas loss is occurring, so that the **operator** is made aware that the full set **delivered volume** is not being delivered to the **patient**. The specified test is intended to establish that the signal fulfils both conditions.

The performance of pneumatically powered signals on **pressure-limitation devices** is often significantly affected by the magnitude of the lung compliance. Most audible signals are designed to operate adequately with occlusion of the **patient connection port**, but the most critical condition for high-inflation pressure is when the alveoli are exposed to this pressure. The specified test is designed to simulate this condition.

A.7.2.7 Inspiratory flow

Current resuscitation guidelines reflect the general acceptance that with the higher inspiratory flows (120 l/min) originally advocated, there was a significant risk of insufflation of the **patient's** stomach during ventilation using a facemask. The current thinking is that flows of approximately 30 l/min should be used during adult **cardiopulmonary resuscitation** [11] [12].

A.7.2.10 Patient-triggered resuscitator

If a claim is made that a **resuscitator** is capable of **patient-triggering**, the breathing effort to initiate triggering needs not to be excessive. Otherwise, the expectation as to the benefit to the **patient** will be exaggerated.

A.8.2.1 Legibility of markings

Markings on **resuscitators** are expected to be **clearly legible** by an **operator** over the range of normal illumination levels where the **resuscitator** is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design:

— 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;

— 500 lx to 1 000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;

— 1 000 lx to 2 000 lx is recommended for visual tasks of low contrast or very small size, e.g. reading handwriting in hard-pencil on poor-quality paper.

If markings are not legible to the **operator** under the expected conditions of use, there would be an unacceptable risk.

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

A.8.2.2 Durability of markings

The rubbing test is performed with distilled water, methylated spirits and isopropanol.

Methylated spirits is ethyl alcohol, denatured with a small quantity (typically < 10 %) of methyl isobutyl ketone or methanol, generally with additional chemicals to give an unpleasant taste and a colour to indicate the product is not suitable for drinking. One formulation in use is composed of:

— specially denatured alcohol 3A (SDA3A) — 94,8 % by volume,

— methanol, 100 % (recognized analytical grade) — 4,7 % by volume, and

— pyridine (recognized analytical grade) — 0,5 % by volume.

Isopropanol is defined in the European Pharmacopoeia as a reagent in the following terms:

— C_3H_8O (MW60.1) — Propanol.

— Isopropyl alcohol: a clear colourless liquid with a characteristic odour, mixable with water and with alcohol.

— It has a relative density of 0,785 at 20 °C, boiling-point 82,5 °C at 101,3 kPa.

A.8.3.2.1 b) Operational instructions and information

The manufacturer should consider that the **patient's** safety can be dependent upon the operation of the **pressure-limiting device** and that it is therefore important that its function is tested by the **operator** prior to use of the **resuscitator**, in accordance with an indicated procedure.

Annex B
(normative)

Test methods

B.1 Test conditions

B.1.1 General

Ensure that the ambient temperature for the duration of the tests is between 20 °C and 25 °C, except where otherwise stated. Ensure that the relative humidity is within the range from 45 % to 75 %, except where otherwise stated.

B.1.2 Conditioning of resuscitator set and test apparatus

Unless otherwise specified in particular tests, place the ***resuscitator set*** *and test apparatus in the test location and allow sufficient time for the* ***resuscitator set*** *and apparatus to reach equilibrium with ambient conditions.*

B.1.3 Reference conditions

Correct all test readings to the reference conditions of normal temperature and pressure, dry (NTPD) {20 °C, 101 325 Pa [1 atm[1)]], 0 % relative humidity}.

B.2 Apparatus

B.2.1 General

Typical test apparatus is shown in Figures B.1 to B.4; alternative test apparatus of equivalent or greater accuracy may be used.

B.2.2 Elements of the test apparatus

The typical test apparatus shown in Figures B.1 to B.4 consists of the following:

a) **test lung** (see Figures B.1 and B.2 for examples), with appropriate compliance and resistance characteristics (see Tables B.1 and B.2);

b) **resistors**, if not provided with the test lung;

c) apparatus for the measurement and the recording of pressure, flow and volume;

d) apparatus for the measurement of temperatures;

e) **graduated cylinder**, of at least 200 ml capacity;

f) oxygen monitor;

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1) The unit "atm" is deprecated.

g) **water reservoir**, sufficiently large to permit complete immersion of the **resuscitator**;

h) **environmental chamber**, capable of maintaining temperatures from (–40 ± 1) °C to (+60 ± 1) °C and relative humidity in the range between 45 % and 75 % and at 95 % (or the ranges indicated in the **accompanying documents**, if greater);

i) **subatmospheric-pressure generator**, capable of generating flows up to 100 l/min at 8 hPa below atmospheric pressure (see Figure B.4 for typical example);

j) **oxygen source** (required if the **resuscitator** is supplied with a connector for the **operator** to connect to the gas source), capable of controlling pressure at a terminal outlet over the range of 280 kPa to 1 000 kPa at flows up to 100 l/min;

k) **gas source,** capable of supplying backpressure-compensated flows, controllable within the range 3 l/min to 60 l/min.

B.3 Test procedures

B.3.1 Valve function after contamination with vomitus

B.3.1.1 Test material

Prepare simulated vomitus by mixing two parts of baby meal beef with vegetable and one part water.

B.3.1.2 Procedure

Warm the simulated vomitus to (37 ± 3) °C and pour 175 ml into the ***patient connection port****. Some of the test solution may spill over when poured into the* ***patient connection port****. Cycle the* ***resuscitator*** *at the maximum cycling rate that can be set with the* ***resuscitator*** *controls. Perform this test with the* ***resuscitator*** *connected to the test lung [B.2.2 a)], selecting the settings for compliance and resistance as appropriate to the* ***delivered volume*** *used, in accordance with Tables 1, B.1 and B.2. Continue to cycle the* ***resuscitator*** *for 30 s. Clear the* ***resuscitator*** *of the mixture according to the* ***accompanying documents*** *and verify the* ***resuscitator's*** *performance.*

B.3.2 Dismantling and reassembly

Verify by inspection of the ***accompanying documents*** *that a functional test has been provided to test operation after reassembly. Simulate possible* ***resuscitator*** *misassembly scenarios, e.g. the omission of a valve element, and verify that the test indicates the misassembly.*

B.3.3 Storage and operating conditions

B.3.3.1 General

Following completion of each phase of the test, operate the ***resuscitator*** *under the conditions indicated in the* ***accompanying documents*** *and verify performance in accordance with 5.1.10, 7.2.2, 7.2.4 and 7.2.6.*

If the ***accompanying documents*** *indicate an operating temperature range wider than –18 °C to +50 °C, then that temperature range is substituted appropriately in B.3.3.2.*

These tests may be performed in any order and on different resuscitators.

B.3.3.2 Procedure

Prepare the ***resuscitator set*** *in accordance with B.1. Place the* ***resuscitator set*** *in the environmental chamber [see B.2.2 h)] and set at either 50 °C or at the maximum temperature stated in the* ***accompanying***

***documents** (see B.3.3.1), and in both cases, at minimum 95 % relative humidity. Maintain these conditions for no fewer than 6 h. At the end of this period, operate and test the **resuscitator set** at this temperature.*

*Place the **resuscitator set** in the environmental chamber set at –40 °C for at least 6 h.*

*At the end of this period, place the **resuscitator set** in an ambient temperature between 20 °C and 25 °C at a relative humidity between 45 % and 75 %. Allow the **resuscitator set** to stabilize for at least 4 h. At the end of this period, operate and test the **resuscitator**.*

*Place the **resuscitator set** in the environmental chamber at 60 °C and at a relative humidity between 40 % and 70 % for not less than 4 h.*

*At the end of this period, place the **resuscitator set** in ambient conditions of 20 °C to 25 °C at a relative humidity between 45 % and 75 %. Allow the **resuscitator set** to stabilize for 4 h. At the end of this period, operate and test the **resuscitator**.*

*Place the **resuscitator set** in the environmental chamber set at either –18 °C or the minimum temperature stated in the **accompanying documents** [see 6.2 and 8.3.2.4 i)] for 4 h. At the end of this period, operate and test the **resuscitator** at this temperature.*

B.3.4 Drop test

*Take any part(s) of the **resuscitator** intended to be removed from its (their) carrying container for resuscitation use and allow it (them) to drop from a height of 1 m onto a concrete floor in the worst-case orientation. Repeat three times.*

*Replace all parts into the supplied or recommended **resuscitator set**. Drop the set, configured for carrying for **normal use**, from a height of 0,75 m onto a concrete floor. Repeat the test three times in the three, mutually perpendicular, worst-case orientations. For this drop test use an empty oxygen cylinder or an "equivalent-mass dummy".*

B.3.5 Immersion in water

*Arrange the **resuscitator** in its ready-for-use condition and drop it from a height of 1 m into the water reservoir [B.2.2 g)]. Take the **resuscitator** out after 10 s and remove the water by shaking for not more than 20 s. Begin ventilating the test lung immediately.*

B.3.6 Gas container capacity

*Using the test arrangement described in B.3.7 ventilate the test lung, starting with a full gas cylinder of the type recommended for use in the **resuscitator set**. Measure the **delivered volume** and the oxygen concentration delivered to the test lung [B.2.2 a)] during the test. Count the number of breaths delivered before the gas supply fails. Multiply the mean volume by the number of breaths to calculate the total volume of gas delivered to the **patient**.*

B.3.7 Delivered oxygen concentration

*Supply the **resuscitator** with oxygen as the driving gas and select the highest oxygen concentration setting (if selectable). Connect it to the test lung [B.2.2 a)], set to the values of compliance and resistance specified in Tables 1, B.1 and B.2. Connect an oxygen monitor [B.2.2 f)] at a site in the compliance chamber as far away as possible from the **patient connection port**. Ventilate the test lung at the **delivered volumes**, frequencies and inspiration:expiration ratios given in Table 1. For those **resuscitators** for which the breathing parameters are not independently variable, set the **delivered volume** to the appropriate value given in Table 1. Record the readings of the oxygen monitor when they become stable.*

*For **resuscitators** with no adjustment of **delivered volume**, use the preset settings.*

B.3.8 Resistance to spontaneous breathing

B.3.8.1 Inspiratory resistance

Using an apparatus such as that shown in Figure B.4 (with valve V held permanently open), for ***resuscitators*** *suitable for use with* ***patients*** *with a body mass of up to 10 kg, connect the* ***patient connection port*** *to the vacuum source and adjust the airflow to 6 l/min.*

For all other ***resuscitators****, connect the* ***patient connection port*** *to the vacuum source and adjust the airflow to 60 l/min.*

During normal operation of the ***resuscitator****, record the pressure generated at the* ***patient connection port*** *during the* ***expiratory phase****.*

B.3.8.2 Spontaneous breathing during power outside of rated range

Repeat the tests described in B.3.8.1 and B.3.8.3, using flows of 30 l/min or 3 l/min, while the gas supply to the ***resuscitator*** *is varied throughout the ranges 280 kPa to 0 kPa and 600 kPa to 1 000 kPa.*

For ***resuscitators*** *conforming to 6.5.5, test with the cylinder contents, reducing from the minimum* ***rated*** *pressure until the cylinder is empty and with 1 000 kPa supplied to the* ***resuscitator*** *to simulate regulator failure.*

B.3.8.3 Expiratory resistance

For ***resuscitators*** *suitable for use with* ***patients*** *with a body mass of up to 10 kg, connect the* ***patient connection port*** *to a gas source [B.2.2 k)] and introduce air at a flow of 6 l/min.*

For all other ***resuscitators****, connect the* ***patient connection port*** *to the gas source and introduce air at a flow of 60 l/min.*

During normal operation of the ***resuscitator,*** *record the stabilized pressure at the* ***patient connection port*** *during the* ***expiratory phase****.*

B.3.9 Inadvertent PEEP

Using the test arrangement described in B.3.7, ventilate the test lung for five consecutive breaths. Measure and record the pressure in the test lung at the end of expiration.

B.3.10 Inadvertent continuing expiratory pressure

Simulate the effect of contamination causing the inspiratory valve to back-leak by fixing a 1,0 mm diameter × 5,0 mm long cylinder of lightweight material in between the sealing faces of the valve element at a point of maximum opening, ensuring that it does not affect the operation of the valve other than allowing back leakage.

Connect the ***resuscitator*** *to the test lung [B.2.2 a)], set to the specified values of compliance and resistance (see Tables 1, B.1 and B.2). Ventilate the test lung at the maximum* ***delivered volume*** *setting of the* ***resuscitator****.*

Verify that the end-expiratory pressure does not exceed 2 hPa (2 cm H_20*).*

B.3.11 Delivered volume

B.3.11.1 With the **resuscitator** supplied with gas from the gas cylinder regulator that is provided or recommended in the **accompanying documents** (6.5.3), measure the **delivered volume** from the **resuscitator** in accordance with the requirements of 5.1.10 and 7.2.2 using test lungs (see Figures B.1 and B.2), with compliances and resistances appropriate to the **delivered volumes** as specified in Tables 1, B.1 and B.2.

B.3.11.2 *Additionally, for* ***resuscitators*** *provided with a probe for connection to a medical gas supply system, connect the probe to the controllable gas source [B.2.2 j)] and retest the* ***resuscitator*** *in accordance with 5.1.10 and 7.2.2, while varying the supply pressure over the range specified in 6.5.4.*

For ***resuscitators*** *with no probe, retest in accordance with 5.1.10 and 7.2.2 while the gas cylinder pressure is allowed to vary through the specified range required in 6.5.5.*

B.3.11.3 *Repeat B.3.11.3 after the drop tests described in B.3.4 and following each phase of the test described in B.3.3.*

NOTE In the absence of leaks (which is the case in the testing conditions), V_{del} has the same value as the simulated tidal volume.

B.3.12 Consistency of delivered volume

Supply the ***resuscitator*** *with oxygen as the driving gas and connect it to a test lung with compliance C20 and resistance R20 (see Tables B.1 and B.2.). Check that the* ***resuscitator*** *is set to deliver greater than 85 % O_2. Ventilate the test lung with a* ***delivered volume*** *of 600 ml and at the frequencies and inspiration:expiration ratios given in Table 1. For those* ***resuscitators*** *for which the breathing parameters are not independently variable, set the* ***delivered volume*** *to 600 ml. For* ***resuscitators*** *with no adjustment of* ***delivered volume****, use the preset settings.*

Measure the ***delivered volume****. Change the test lung to C50, R10, with no change to the* ***resuscitator*** *settings (for* ***manually-cycled resuscitators****, maintain a constant rate of manual triggering), and again measure the* ***delivered volume****. Record the difference between the two readings.*

B.3.13 Pressure limitation and high-pressure alarm

B.3.13.1 *The following procedure is applicable to* ***resuscitators*** *that limit pressure, under* ***normal use****, by means of a relief valve.*

a) If adjustable, set the **pressure-limiting device** to its highest setting.

b) For **resuscitators** classified for use with **patients** up to 5 kg body mass, occlude the **patient connection port** and the **exhaust port**. Using the compressed air source [B.2.2 k)], pass air at a flow of 15 l/min through the **pressure-limiting device**. Record the pressure at the **patient connection port**.

c) For **resuscitators** classified for use with **patients** of over 5 kg body mass, occlude the **patient connection port** and the **exhaust port**. Using the compressed air source, pass air at a flow of 60 l/min through the **pressure-limiting device**. Record the pressure at the **patient connection port**.

d) Check that the high-pressure alarm sounds each time the **pressure-limiting device** is activated.

e) Ventilate a C50, R0 test lung with a **delivered volume** of 600 ml (or the preset volume for non-adjustable **resuscitators**, or the maximum volume of a child **resuscitator**). Without changing the **resuscitator** settings, connect the **resuscitator**, in turn, to a C20, R0 and a C10, R0 test lung.

f) Select the lowest compliance lung that did not cause the alarm to sound and ventilate, without changing the **resuscitator** settings, with the test arrangement shown in Figure B.3. Adjust the valve until the alarm just sounds and record the volume then being delivered to the test lung.

g) Verify that the reduction in **delivered volume** does not exceed 25 % and that the requirements of 7.2.4, 7.2.5 and 7.2.6 are satisfied.

B.3.13.2 *The following procedure is applicable to* ***resuscitators*** *that limit pressure, under* ***normal use****, by terminating flow or switching from inspiration to expiration.*

a) Measure the pressure at the **patient connection port**, while testing for alarm function as indicated in the **accompanying documents**. See also 8.3.2.1 b).

b) Connect the **resuscitator** to a test lung appropriate for the maximum body mass indicated in the **accompanying documents**, as specified in Table 1, and ventilate using the settings that generate maximum pressure at the **patient connection port**.

c) Without changing the **resuscitator** settings, disconnect the **resuscitator** from the test lung and measure the pressure at the **patient connection port** with the port occluded.

d) Verify that the requirements of 7.2.4, 7.2.5 and 7.2.6 are satisfied.

B.3.14 Inspiratory flow

Connect a flowmeter with a variable flow restrictor upstream to the ***patient connection port****, by means of a 22 mm hose incorporating a pressure gauge. Operate the* ***resuscitator*** *with maximum oxygen concentration selected, if selectable, and adjust the restrictor to give, in turn, an output pressure of 20 hPa (20 cm* H_2O*) and* < 3 *hPa. Verify that the flow requirements specified in 7.2.7 are met at both output pressures.*

B.3.15 Operation of manual trigger

Have three adults, with hands no larger than the maximum dimensions allowed as shown in Figure B.5, apply successively the recommended facemask to the face of a ***cardiopulmonary resuscitation*** *training mannequin, in accordance with the requirement specified in 7.2.8, and operate the triggering mechanism with one finger only for 30 consecutive adult inflation cycles.*

Tests are to be performed with all configurations of the ***equipment*** *recommended in the* ***accompanying document*** *which can affect the outcome of this test.*

Ensure that the operation of the ***resuscitator*** *in this manner allows the same lung inflation to be achieved as that obtained by a second* ***operator*** *operating the mechanism fully using both hands, while the first* ***operator*** *maintains mask seal with two hands (two-man operation).*

B.3.16 Demand valve

B.3.16.1 Setup

With the ***resuscitator*** *supplied from the gas source in the supplied or recommended* ***resuscitator set****, connect the* ***patient connection port*** *of the* ***resuscitator*** *incorporating the* ***demand valve*** *to the test apparatus shown in Figure B.4, and test in accordance with B.3.16.2 to B.3.16.4.*

B.3.16.2 Flow threshold

With valve (V in Figure B.4) held open, increase the subatmospheric-pressure control and note the reading on the pressure sensor (P in Figure B.4) at an output flow of 5 l/min.

B.3.16.3 Peak flow

Open valve (V) and set the steady-state demand flow to 100 l/min. Close valve (V). Operate valve (V) so that it opens in a time of less than 20 ms. Record the pressure/flow response of the ***demand valve****. Verify that an output flow of 100 l/min is achieved within 250 ms and is maintained for at least 5 s with a subatmospheric pressure at the* ***patient connection port*** *of* < 8 *hPa.*

B.3.16.4 Flow termination

With valve V held open, adjust the regulator that controls the subatmospheric pressure at the ***patient connection port*** *until the output flow is 5 l/min. Gradually decrease the subatmospheric pressure until flow terminates and record the subatmospheric pressure at which this occurs. If the* ***accompanying documents*** *indicate a positive termination pressure, substitute a positive pressure gauge.*

B.3.17 Patient-triggered resuscitator

Using the test arrangement shown in Figure B.4, set the steady-state pressure at the ***patient connection port*** *to 2,5 hPa (2,5 cm H_2O). With the* ***resuscitator*** *cycling automatically, operate valve (V) so that it opens in a time of less than 20 ms at an appropriate point in the* ***expiratory phase****. Record the pressure/flow response of the* ***resuscitator****. Verify that the* ***resuscitator*** *switches into its* ***inspiratory phase*** *within 250 ms with a subatmospheric pressure at the* ***patient connection port*** *of $<$ 2,5 hPa.*

Table B.1 — Required values for compliant chamber of test lung

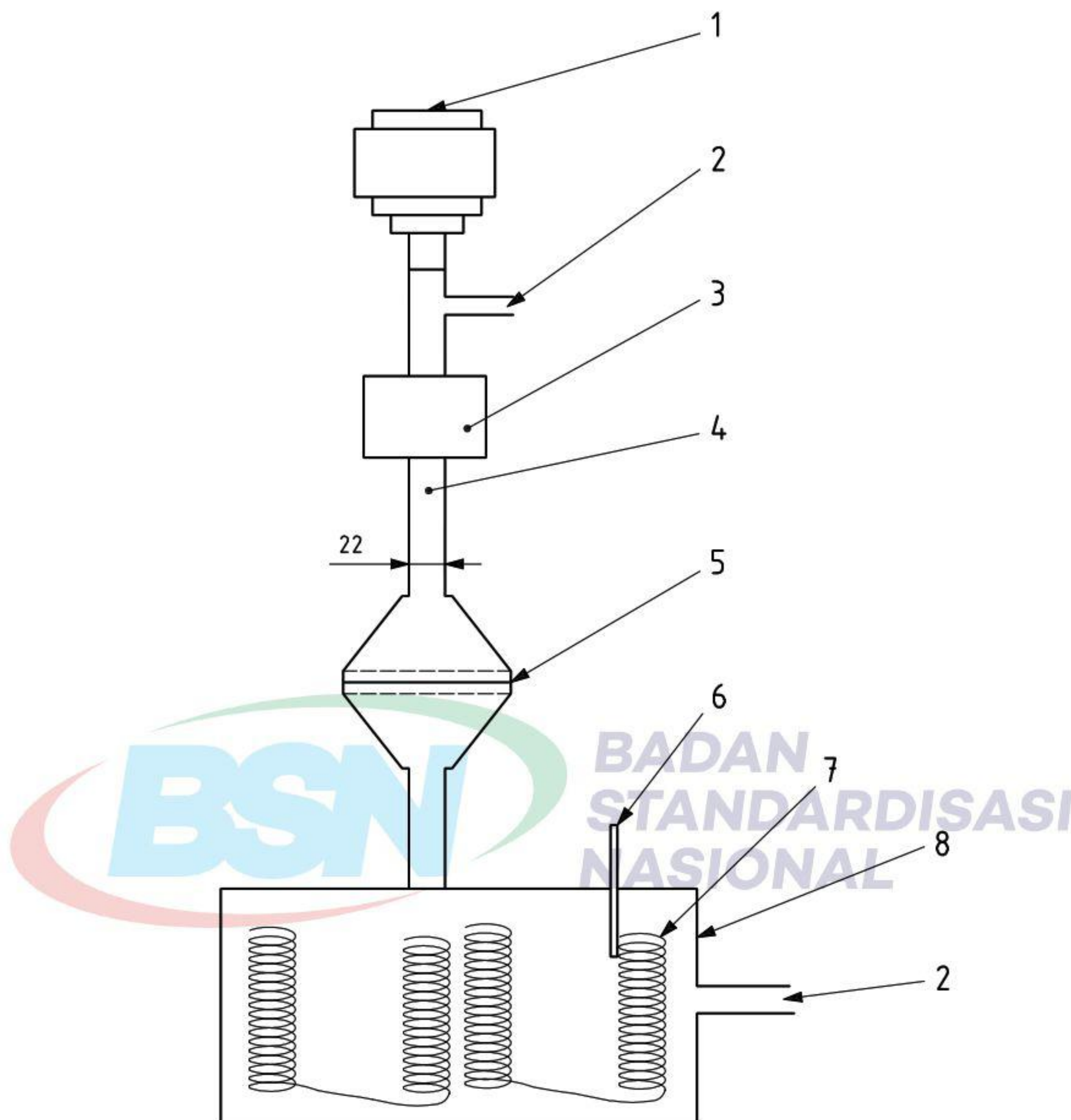
Compliance C designation	Isothermal compliance value l/hPa	Equivalent value ml/cm H_2O	Tolerance %
C50	0,05	50	+10 −5
C20	0,02	20	
C10	0,01	10	
C1	0,001	1	

Table B.2 — Required resistance values for test lung

Resistance R designation	Resistance value hPa/(l/s)	Equivalent value cm H_2O/(l/s)	Airflow range for calibration l/s	Tolerance %
R10	10	10	0,3 to 0,66 [a] and 0,1 to 0,2 [a]	± 20
R20	20	20	0,1 to 0,2	
R200	200	200	0,05 to 0,075	

[a] If a single resistance cannot be calibrated to achieve the required tolerance over both of these flow ranges, separate resistances may be calibrated for each range and then used as appropriate to the resuscitator flow used in the specific test.

Dimensions in millimetres

Key

1 **resuscitator**

2 pressure tapping ports (airway and alveolar)

3 integrating flow-meter to measure tidal volume (optional)

4 non-compliant tubing

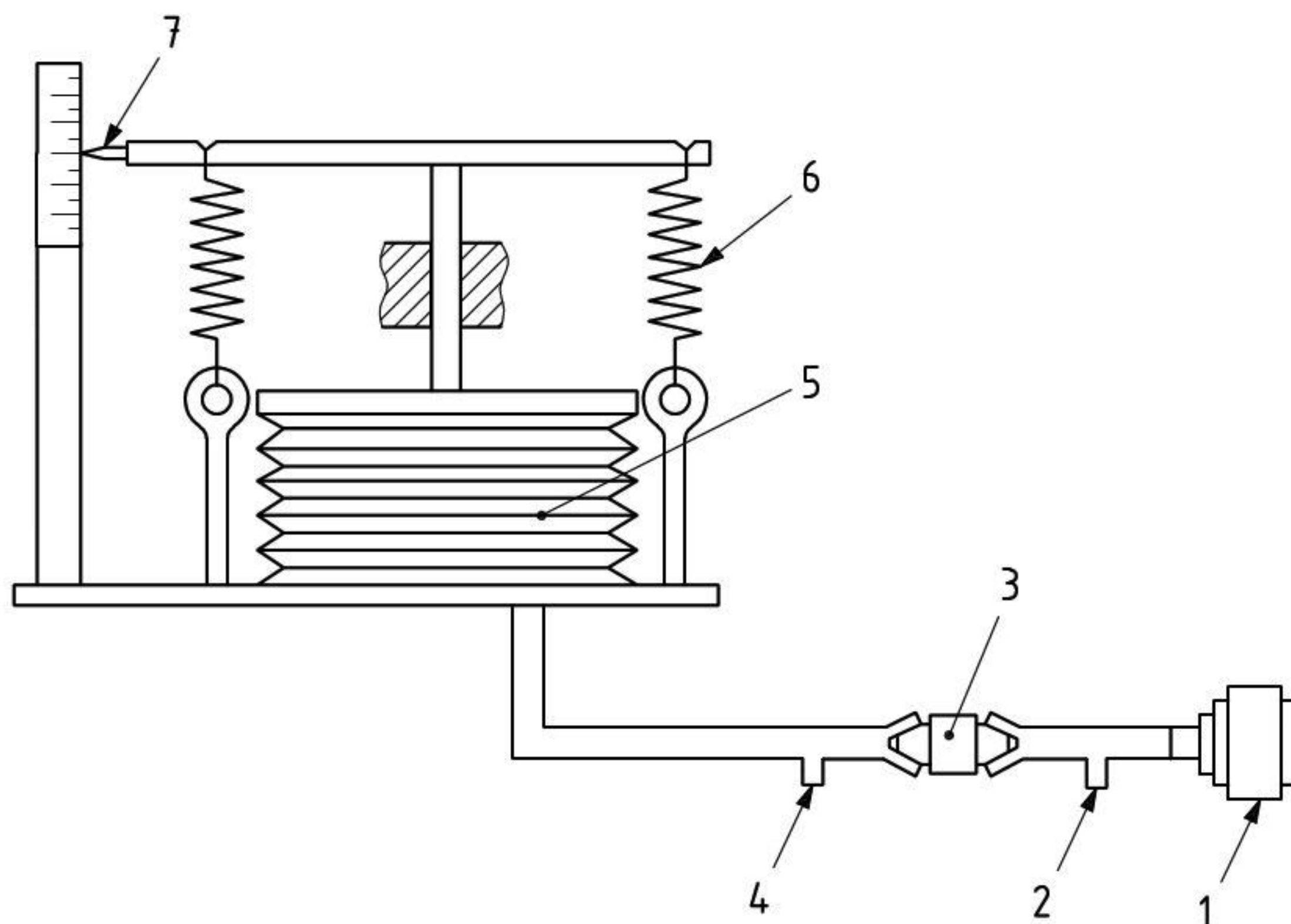
5 interchangeable test lung resistance (R10 to R200)

6 thermometer

7 copper wire to maintain isothermal compression

8 rigid compliance chamber of test lung (C1 to C50)

Figure B.1 — Representative passive test lung system

Key

1 **resuscitator**

2 pressure tapping point (airway pressure)

3 test lung resistance element (R10 to R200)

4 pressure tapping point (alveolar pressure)

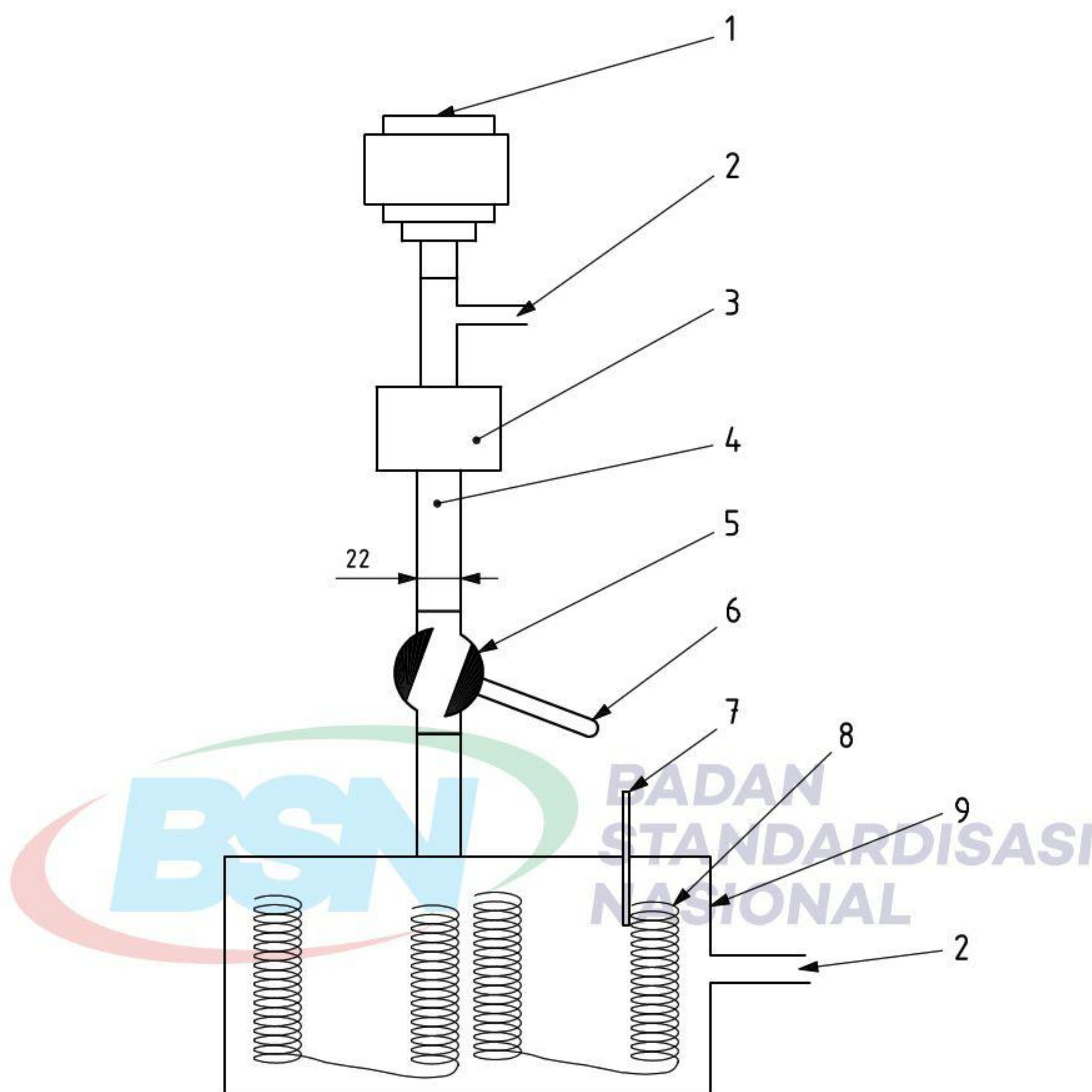
5 expansible test lung compliance element (C1 to C50)

6 settable compliance springs

7 display of tidal volume

Figure B.2 — Example of active test lung system

Dimensions in millimetres

Key

1 **resuscitator**

2 pressure tapping ports

3 integrating flow-meter to measure tidal volume (optional)

4 non-compliant tubing

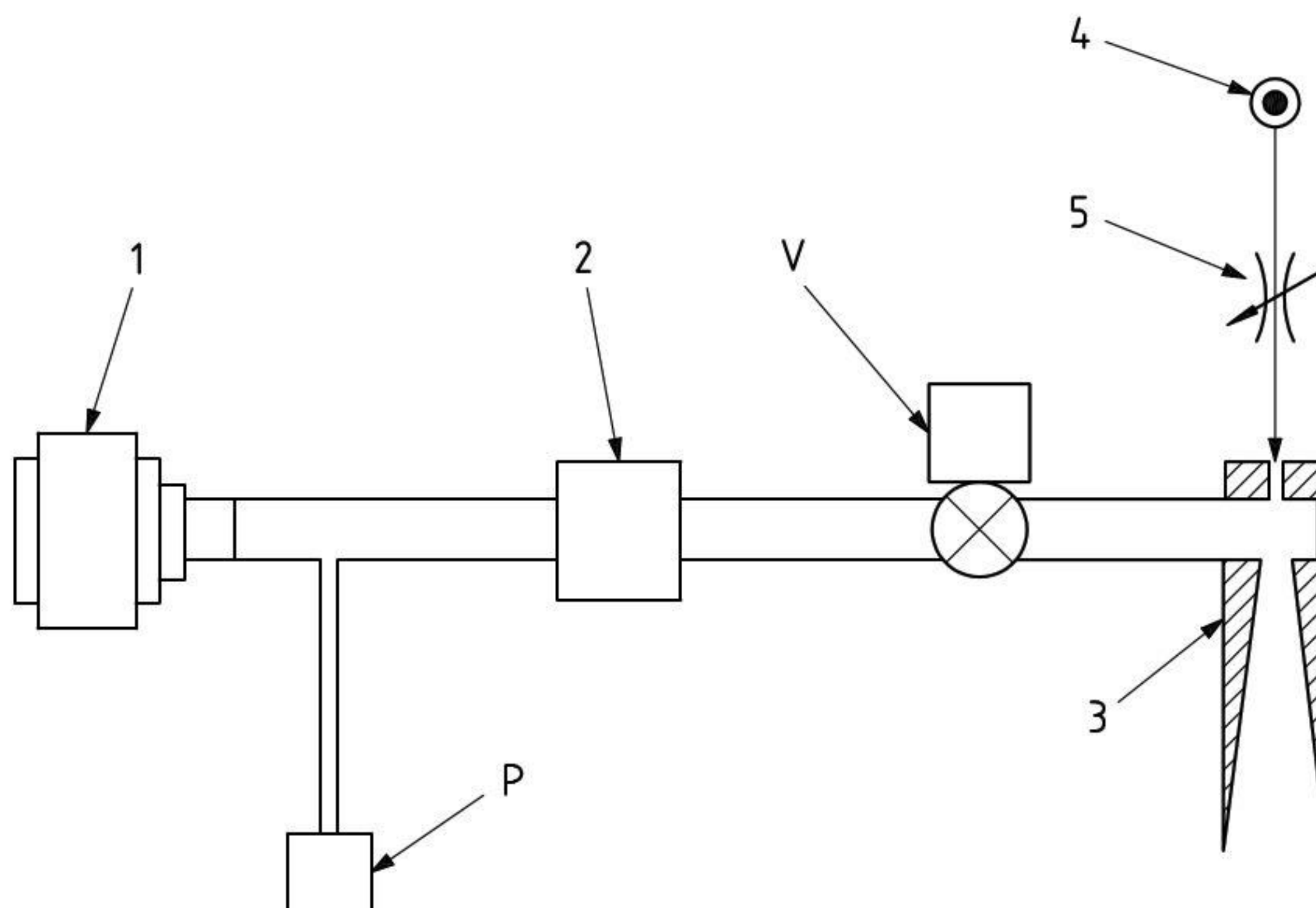
5 valve (e.g. an **operator** adjustable ball valve of typically 19 mm through-bore)

6 actuator for adjusting valve

7 thermometer

8 copper wire to maintain isothermal compression

9 rigid compliance chamber of test lung (C1 to C50)

Figure B.3 — Typical modified test lung arrangement with adjustable ball valve replacing resistance in order to test audible high-pressure alarm

Key

1 **resuscitator**

2 dynamic flowmeter

3 high flow vacuum generator

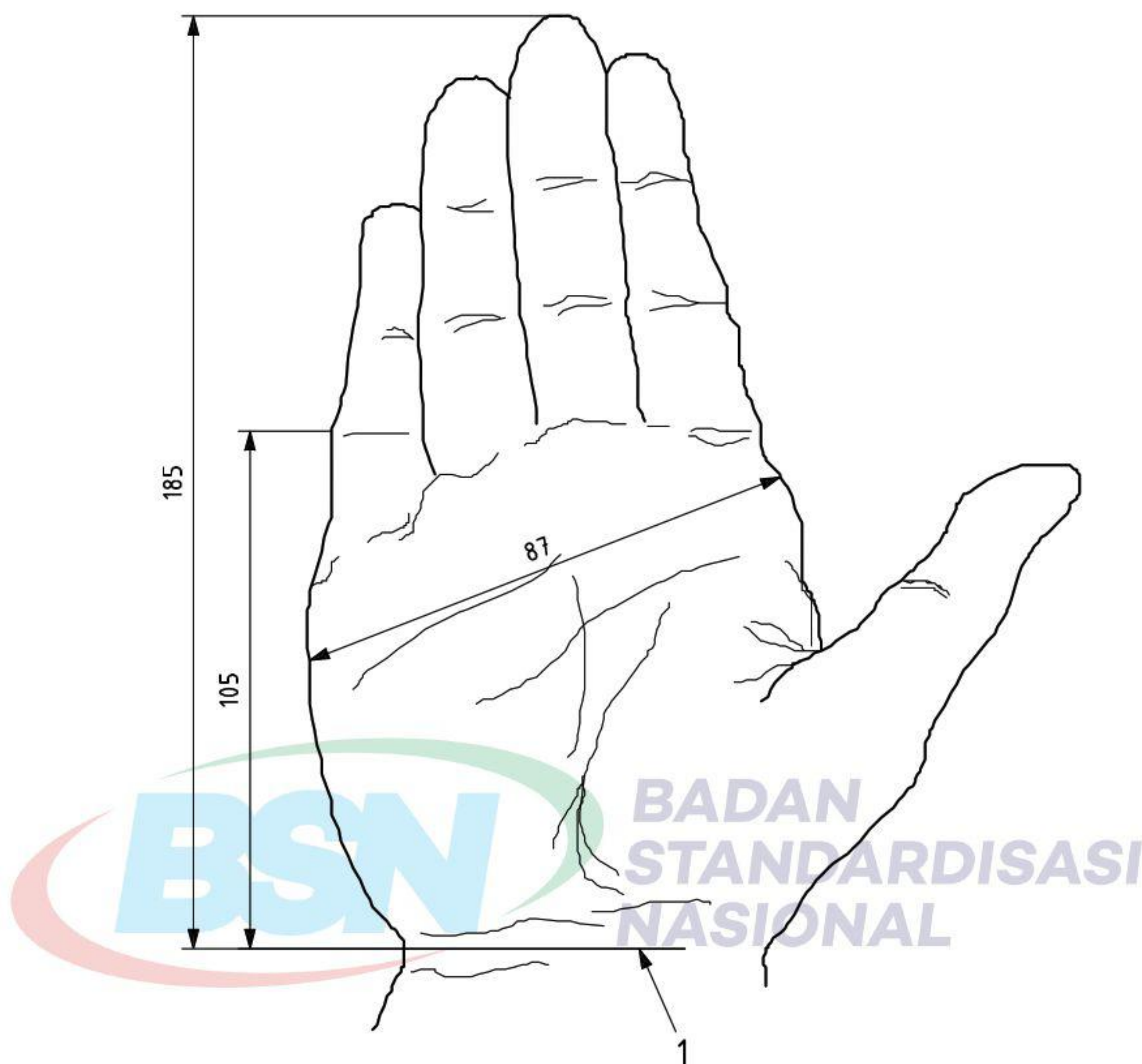
4 pressurized gas source

5 regulator controlling subatmospheric pressure

P dynamic pressure sensor

V shut off valve

Figure B.4 — Example of test apparatus for testing demand valves and patient-triggering

Dimensions in millimetres

Key

1 distal skin crease

Figure B.5 — Maximum hand dimensions

Annex C
(informative)

Relationship between this part of ISO 10651 and cardiopulmonary resuscitation guidelines

As has been stated in rationale A.1, **cardiopulmonary resuscitation** guidelines have been taken into consideration in the preparation of this part of ISO 10651 but, for the reasons stated, it does not limit the design of **resuscitators** to suit them for use with any specific recommendations. However, the following observations may be helpful in establishing where **resuscitators** covered by this part of ISO 10651 fit in with these guidelines.

Over the past 40 years, the concepts of **cardiopulmonary resuscitation** have become widely established as an effective means of treating victims of cardiac arrest. The methods and protocols for achieving these concepts are continually evolving. However, rescue breathing by expired air has always been a key element in the recommendations for the procedure because of its universal availability and applicability. These recommendations place emphasis on the rescuer monitoring the **patient** directly, for both an open airway and for correct ventilation, by watching the chest rise and fall as in normal breathing.

Although always remaining a fundamental procedure in training for **cardiopulmonary resuscitation**, the disadvantages of expired air resuscitation, both perceived and actual, led to the introduction of alternative means for delivering rescue breathing, such as bag-valve-mask and **gas-powered emergency resuscitators**. These devices were seen, however, as performing the same function as expired air techniques, using the same protocols, but offering specific advantages.

Whichever method is used to provide rescue breathing, simplicity of use and wide availability have always been the prime requirements. The use of monitoring adjuncts has not been generally encouraged by **users** specifying **equipment** for the first response personnel likely to be administering rescue breathing, as occurs in many countries throughout the world. This is because such monitoring is considered distracting, and possibly misleading, to such personnel. As an example, rapidly changing lung compliance and resistance during rescue breathing can result in airway pressure measurements bearing little relationship to delivered ventilation. Such indications are, therefore, considered an unnecessary distraction away from the **patient** in the absence of extensive **operator** experience or the additional use of other, more advanced, **equipment**.

To avoid confusion when referring to both this part of ISO 10651 (a standard) and to resuscitation guidelines, it should be noted that the terminology used in describing resuscitation **equipment** is often different from that used in guidelines. By their nature, standards use a formal classification whereas, guidelines, because they are aimed at training lay personnel, use terms in common use. In particular, some references use the term “transport ventilator” to cover all automatic resuscitation devices although the accompanying texts make it clear that the devices being referred to come within the scope of “**gas-powered emergency resuscitators**” in this series of documents. Similarly, references to oxygen-powered, manually-triggered devices (inappropriately called **demand valves** in some countries) describe both satisfactory and unsatisfactory devices that are available commercially. It is one of the objectives of this part of ISO 10651 to exclude devices with the unsatisfactory characteristics that have been identified.

Annex D
(informative)

Clauses of this part of ISO 10651 addressing the essential principles

This part of ISO 10651 has been prepared by ISO TC121/SC3 and supports the essential principles of ISO/TR 16142.

WARNING — Other requirements and other documents *may* be applicable to the product(s) falling within the scope of this part of ISO 10651.

The following clauses of this part of ISO 10651 are likely to support requirements of the essential principles of ISO/TR 16142:1999.

Compliance with the clauses of this part of ISO 10651 provides one means of conforming with the specific essential principles of ISO/TR 16142:1999.

Table D.1 — Correspondence between this part of ISO 10651 and ISO/TR 16142:1999

Clause/subclause of this part of ISO 10651	Corresponding essential principle of ISO/TR 16142:1999, Annex A	Comments
All	1, 2, 3	
1	6	
4	4, 5, 6, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 8.1, 8.1.1, 8.1.2, 8.2, 8.3, 8.4, 8.5, 8.6, 9.1, 9.2, 9.3, 12.2, 12.3, 12.7.1, 12.7.2, 12.7.3, 12.8.1, 12.8.2, 12.8.3, 13.1	
5.1	4	
5.1.1	7.2, 7.3	a
5.1.2	9.2	
5.1.3	7.2, 7.3, 7.5	a
5.1.4	9.1	
5.1.5	8.2, 8.3, 8.4, 8.5, 8.6	
5.1.6	8.1, 9.1	
5.1.7	2, 12.1	
5.1.8	5, 9.2, 12.8.3	
5.1.9	5, 9.2, 12.8	
5.1.10	12.8.1	
5.1.11	9.1	
5.2	9.1, 9.2, 12.7.3	
6.1	4, 7.6, 9.2	
0	8.1	
6.3	4, 5	
6.3.2, 6.3.3	7.6	
6.4	9.2	

Table D.1 (*continued*)

Clause/subclause of this part of ISO 10651	Corresponding essential principle of ISO/TR 16142:1999, Annex A	Comments
6.5	9.1	
6.5.1	7.4, 9.2	[b]
6.5.3	9.2, 9.3, 12.2, 12.3, 12.7.3, 12.8.2	
6.5.4	9.2, 12.7.3	
6.5.5	9.2	
7	12.8	[c]
7.1.2	12.2, 12.3	[c]
8	5	
8.1.2	10	
8.2	4, 12.8.3	
8.2.1, 8.2.2, 8.2.3	9.1	
8.3	13.1	
8.3.2.1	9.1	
8.3.2.3	6	
8.3.2.3 d)	9.1	
8.3.2.3 e)	9.3	
8.3.2.5	4	

[a] The only contact between these devices and body tissues and fluids is via an **accessory** (separate medical device) such as a facemask. Because of the intended use, the contact time is always short.

[b] National pharmacological quality assurance procedures for the filling of medical gas cylinders ensure that gas cylinders with valves complying with ISO 10297 contain gas of approved quality. Resuscitation guidelines strongly recommend the use of high oxygen concentrations for resuscitation. This part of ISO 10651 does not exclude the use of other medical gases, e.g. medical air. The suitability of a specific medical gas for a specialist purpose is outside the scope of this part of ISO 10651.

[c] The safety of the **patient** is not dependant on the gas power supply and an inadequate gas flow to the **patient** does not pose a danger to the **patient** because this part of ISO 10651 specifies safeguards to cover these eventualities and the **operator** is constantly in attendance. These safeguards are used as alternatives to supply indicators and alarms because, consistent with the requirement of Essential Principle 1 and the intended use of these devices, **users** consider that simplicity, compactness and **operator** observation of the **patient** are the prime considerations. See also Annex A.

Annex E
(informative)

Terminology — Index of defined terms

BSN
BADAN
STANDARDISASI
NASIONAL

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[8] ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

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